IAHCSMM

International Association of Healthcare Central Service Materiel Management

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MEMORANDUM

TO: Larry Spears
Director, Enforcement III
DATE: December10, 1999
RE: IAHCSMM Response to FDA's Proposed Strategy on Reuse of Single-Use Devices (SUD's)

The purpose of this memorandum is to provide feedback from IAHCSMM on the FDA's Proposed Strategy on Reuse of SUD's.

IAHCSMM, with a membership of approximately 8,400 professionals, is the largest organization in the nation representing sterile processing technicians, supervisors and directors. Our Position Paper on the Reuse of SUD's was presented at the AAMI/FDA meeting held in May, 1999. To this point, our position has not changed; IAHCSMM continues to discourage the practice of healthcare facilities becoming involved in the reprocessing of single-use devices and does not recommend it. Should the need to reduce expenses cause a healthcare facility to become involved in the reuse of SUD's, IAHCSMM recommends using the services of a third-party reprocessor registered with the FDA and able to meet the criteria established by a multi-disciplinary healthcare reuse committee.

Our Position Paper is based on IAHCSMM's belief that the average healthcare sterile processing department would find it extremely difficult to comply with the FDA Compliance Policy Guide 300.500 requiring demonstration that the device can be adequately cleaned and sterilized, that the quality of the device will not be adversely affected, and that the device remains safe and effective for its intended use.

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Section 1. Reconsider the agency's current policy on establishments that reprocess SUDs.

In response to the FDA's Proposed Strategy, IAHCSMM favors regulation of third-party reprocessors and healthcare facilities that engage in reprocessing SUD's, and disclosure of the items being reprocessed. IAHCSMM considers the reprocessing of SUD's in healthcare facilities to be a serious patient safety issue, and offers the following rationale for the need for regulation:

- It is estimated that over 50% of healthcare facilities are reprocessing SUD's with limited accountability, using reprocessing procedures that may or may not be adequate.

- Performance standards for sterile processing vary from one institution to another, and are not necessarily based on good science. This was described by one of our members in this way: "All healthcare facilities are not created equal ....we have no one way or set of guidelines to reprocess specific items". The majority of healthcare facilities rely on manufacturers' recommendations to establish their reprocessing protocols. Obviously, SUDs have no reprocessing instructions. There is little or no information provided by the original equipment manufacturer (OEM) regarding the materiels used in the manufacture of the device. There are no disassembly or reassembly instructions. Also lacking is information on the compatibility of cleaning and sterilization agents. All of this must be established in order to properly reprocess the device, and it is often beyond the capability of the sterile processing staff.

- Consensus standards, such as those developed by the Association for the Advancement of Medical Instrumentation (AAMI) are available to healthcare facilities, but they are voluntary standards. Only the State of New Jersey mandates that AAMI Recommended Practices be followed and inspects to insure compliance.

- Another concern is the lack in most of our healthcare sterile processing departments of a quality system that identifies all the critical aspects of the reprocessing function, puts controls in place, and creates a process that is completely reproducible from beginning to end. There is an AAMI Working Group currently developing a Technical Information Report which will address the requirements of a quality system for our healthcare facilities, but at present there is a great deal of misunderstanding of what constitutes an acceptable quality system.

Section 2. Explore the development of a device categorization system based on the level of risk presented by reprocessing and reusing SUDs and an enforcement strategy based on the level of risk.

- Healthcare facilities are accustomed to considering categories in terms of the CDC's Guideline for Handwashing and Hospital Environmental Control, 1985, which classifies medical devices, equipment, and surgical materials into three categories: critical, semi-critical and non-critical items based on the potential risk of infection involved in their use. Under this device categorization system, the following definitions are understood:

(1) Critical – Instruments or objects that are introduced directly into the bloodstream or into other normally sterile areas of the body.
(2) Semi-critical- Items that come in contact with intact mucous membranes; they do not ordinarily penetrate body surfaces.
(3) Non-critical – Items that either do not touch the patient or touch only intact skin.

We recommend that these factors be included in determining the risk categories for SUDs.

- IAHCSMM agrees that the quality and extent of published data on reprocessing for the specific device should be considered in its classification **if the published data is non-biased, academic, and written by an individual without financial interest in the device.**

- IAHCSMM agrees that the complexity of procedures associated with reprocessing the device should be considered in its classification, **including the potential of the device to retain sterilant, or to lose any of its properties through reprocessing.**

- We have some concern about "Low-Risk" reprocessed SUDs from the standpoint that there should be documented testing to determine accurately how many times a "low-risk" device can be reprocessed and still remain safe and effective for its intended use. The expensive lawsuit over the broken reprocessed single-use bedpan is an example of what can happen to a "low risk" device that may have been reprocessed too many times and caused considerable harm to the patient.

Section 3. Solicit comments on the FDA's draft "List of Frequently Reprocessed SUDs".

- IAHCSMM has no comments to make regarding the proposed list.

Section 4. Consider requesting OEMs to provide information on their labels about risks associated with reuse of SUDs.

- IAHCSMM felt it would be very helpful if OEMs who label their devices "single-use" would provide, as part of the device's labeling, any information of which they are aware regarding the potential risks associated with reusing their SUDs. It would be helpful, too, if the information was affixed in some way to the device. Unfortunately, enclosures may be discarded with the packaging by mistake when devices are unpacked in the Receiving area.

Section 5. Examine the need to create working definitions for the terms "single-use device", "reuse", "reprocessing", and "resterilization".

- IAHCSMM accepts the working definitions the agency is considering, and is satisfied with the wording of each term.

Section 6. Explore how recognized consensus standards can be applied to reprocessing SUDs (e.g., to verify and validate cleaning, disinfection and/or sterilization of SUDs) and explore the development of additional consensus standards to address the safety, effectiveness, and performance of reprocessed SUDs.

- IAHCSMM acknowledges this is an essential element of the Proposed Strategy. We are most familiar with AAMI standards as we actively participate on AAMI committees as "users". ECRI has also done a lot of work in this area. Perhaps it would be possible to develop a working group along the lines of an AAMI committee to develop standards and present them for approval. Please let us know if we can be of any assistance.

Section 7. Consider developing a research program on reuse of SUD's and explore avenues to publish and disseminate research and other information on reuse.

- IAHCSMM encourages any effort made by the agency to disseminate information on its activities. The Internet is a very popular way to communicate, and we are continuing to develop our website. We also have a publication, *Communiqué*, which is mailed bi-monthly to our membership.
  These are open to you if you have information on reuse that you would like to disseminate to our members, such as the development of a research program on reuse of SUDs. Some of our members may work in healthcare facilities that would be interested in such a project.

We appreciate the opportunity to comment on the FDA's Proposed Strategy on Reuse of SUDs. Should you have any questions regarding our comments, please do not hesitate to contact our Executive Director, Betty Hanna.